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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIPHER PHARMACEUTICALS, INC., GALEPHAR PHARMACEUTICAL RESEARCH, INC., RANBAXY, INC., and RANBAXY PHARMACEUTICALS, INC., Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., ANDRX CORP., ACTAVIS, INC., and ACTAVIS PHARMA, INC., Defendants.	Civil Action No. 13-6502 (JEI)(AMD) (Consolidated)

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF
FOR U.S. PATENT NOS. 8,367,102 AND 7,435,427

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Plaintiffs Cipher Pharmaceuticals, Inc., Galephar Pharmaceutical Research, Inc., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively, "Plaintiffs") respectively submit their Opening Claim Construction Brief in support of their proposed construction of terms of U.S. Patent No. 8,367,102 ("the '102 patent") and U.S. Patent No. 7,435,427 ("the '427 patent").[1]

I. INTRODUCTION

Plaintiffs are the innovators of the prescription medication Absorica®, which is indicated for the treatment of severe recalcitrant nodular acne in patients twelve years of age and older. The United States Food and Drug Administration ("FDA") approved Plaintiffs' New Drug Application ("NDA") No. 21-951 for Absorica® on May 25, 2010, and granted Plaintiffs a three-year new product exclusivity period for conducting new clinical investigations that were essential to approval of the new drug. In connection with the NDA for Absorica®, Plaintiffs listed the '102 patent and '427 patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book").

The '427 patent contains claims directed to oral pharmaceutical compositions of isotretinoin that are *semi-solid suspensions*. The '102 patent, which is a continuation of the '427 patent with the same specification, contains claims directed to methods of treating a skin disorder with an oral pharmaceutical composition of isotretinoin. Unlike the '427 patent, certain claims of the '102 patent cover isotretinoin compositions that are semi-solid preparations that include, but are not limited to, suspensions (e.g., claims 1-4, 6-9, and 17), while other claims are directed specifically to isotretinoin compositions that are semi-solid suspensions (e.g., claims 13-15).

[1] The '102 and '427 patents are attached to the Declaration of Martyn C. Davies, Ph.D. in Support of Plaintiffs' Opening Claim Construction Brief ("Davies Decl.") as Exhibits 1 and 2, respectively.

Plaintiffs have asserted claims 1-4, 6-9, and 13-17 of the '102 patent and claims 1-3, 7-15, and 17 of the '427 patent against defendants Actavis Laboratories FL, Inc., Andrx Corp., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Defendants"), who have filed Abbreviated New Drug Application ("ANDA") No. 205063 seeking the FDA's approval to market generic versions of Absorica®.

The parties recently agreed to the meaning of one previously disputed claim term;[2] however, seven disputes remain.[3] Plaintiffs submit that many of these terms are readily understandable to one of ordinary skill in the art and should be construed according to their plain and ordinary meaning, and the meanings of the remaining terms are set forth in the specification or other intrinsic evidence. Thus, Plaintiffs' proposed constructions follow the tenets of claim construction set forth in the Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*

Defendants, on the other hand, ignore the plain meaning of the disputed terms, and instead resort to unreasonable interpretations that are not supported by, and at times directly contradict, the intrinsic evidence. Their arguments controvert common scientific principles, and embrace constructions that improperly exclude the very embodiments described in the patent. Additionally, in a transparent but futile attempt to invalidate the claims for indefiniteness, Defendants propose lengthy, redundant and self-contradictory alternate constructions or contend that basic claim terms cannot even be reasonably defined. But precedent and common sense, combined with the teachings of the patent, plainly overcome Defendants' unreasonable

[2] The parties recently agreed that the claim term "glycerol macrogolglycerides" should be construed according to its plain meaning: "glycerol or glyceroyl macrogolglycerides are mixtures of monoesters, diesters and triesters of glycerol and monoesters and diesters of macrogol (also called polyethylene glycol)."

[3] There are currently seven claim term disputes, involving nine claim terms in total. As shown below, this is because two sets of claim terms are similar and involve the same disputes.

arguments. As a result, this Court should adopt Plaintiffs' constructions and reject Defendants' interpretations of the claim terms.

II. BACKGROUND OF THE INVENTION

Isotretinoin is a pharmaceutical molecule that is effective in the treatment of severe skin disorders, such as cystic acne. ('102 Patent col. 1 ll. 18-22; '427 Patent col. 1 ll. 11-15; *see also* Davies Decl. at ¶ 10.) In addition to its beneficial effects, however, isotretinoin can also be highly toxic, causing adverse effects such as birth defects, liver toxicity, vomiting, headaches, skin anemia, severe mucosal irritation, and appendicitis. (Davies Decl. at ¶ 11.) Unfortunately, the therapeutic window of isotretinoin is very narrow, meaning that there is a small dosage range between the dose at which isotretinoin is effective and the dose at which it is toxic. (*Id.* at ¶ 24.) Thus, to avoid either ineffective treatment or dangerous toxicity, it is important to have a formulation of isotretinoin that keeps the concentration within the narrow therapeutic window. Compared to other pharmaceutical molecules, isotretinoin is also especially difficult to work with, because the compound degrades when exposed to light and atmospheric oxygen. (*Id.* at ¶ 23.) Thus, scientists developing isotretinoin formulations face a difficult task, owing to the compound's unique toxicity, instability in light and air, and narrow therapeutic window.

For more than two decades the only formulation of isotretinoin available to patients was the Accutane® gelatin capsule, which was largely composed of oily, fatty ingredients such as beeswax and vegetable oil. (*Id.* at ¶ 13 n.2.) Because of its chemical properties, isotretinoin readily dissolved in these oily substances. However, when patients ingested Accutane® capsules, the oily formulation would not mix well in the largely aqueous environment of the human body, leading to poor bioavailability of the isotretinoin active ingredient. (*Id.* at ¶ 19.) It was found that the presence of food—which generally includes a mixture of oils and water soluble molecules—could greatly increase absorption of the drug. (*Id.*) This phenomenon is known as the "food

effect," and Accutane dosage instructions accordingly informed users to take the capsules with food. (*Id.* at ¶ 14.)

The strong food effect of Accutane®, combined with the realities of patients' variable food intake habits and the severe toxicity associated with over-dosage, produced a significant public health challenge. (*Id.* at ¶¶ 14–16.) Patients would experience radical spikes in absorption of the drug when taken with food, which increased the risk of toxicity. (*Id.*) Decreased absorption rates associated with low food intake were also problematic, potentially defeating the purpose of the treatment and causing patients to undergo "re-treatment" thereby increasing their exposure to the toxic substance and prolonging their cystic acne symptoms. (*Id.* at ¶ 16.)

The inventions described in the '427 and '102 patents solved this problem. By creating novel semi-solid formulations containing both a water-soluble component and an oily vehicle, the inventors of the asserted patents made digestible isotretinoin vessels that solved the "food effect" problem. (*Id.* at ¶ 19.) Accordingly, Plaintiffs' Absorica® product is the only isotretinoin product on the market with a dosage instruction that the capsules should be taken "without regard to meals." (*Id.* at ¶ 20.)

Plaintiffs spent years developing the inventions described in the '427 and '102 patents, eventually succeeding in creating a new, safer formulation of isotretinoin where others had tried and failed. For instance, the manufacturer of Accutane®, Hoffmann-La Roche Pharmaceuticals, developed a proposed product named Accutane-NF (new formulation), which was a micronized version of Accutane theorized to increase bioavailability and decrease food effect. (*Id.* at ¶ 17.) However, a clinical trial revealed that Hoffman-La Roche's new formulation was not as effective as the Accutane product and therefore, they never brought the new formulation to market. (*Id.*) Plaintiffs, on the other hand, finally succeeded in developing their Absorica® product after years

of laboratory research and product testing, including multiple human trials required by the FDA to show the improved safety and efficacy of Absorica®'s novel formulation. (*Id.* at ¶¶ 19–20.) Indeed, when Plaintiffs released Absorica® to the public, clinicians and medical societies alike praised the product for its improved pharmacological properties over Accutane, the product that had dominated the market for the preceding two decades. (*Id.* at ¶ 20.)

III. LAW ON CLAIM CONSTRUCTION

"[I]nterpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). When construing the claims of a patent, a court first considers the literal language of the claim, the patent specification and the prosecution history. *Id.* at 979. In *Phillips v. AWH Corp.,* the Federal Circuit reaffirmed the "bedrock principle" of patent law that "[b]ecause the patentee is required to 'define precisely what his invention is,'" "it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'" 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *White v. Dunbar*, 119 U.S. 47, 52 (1886)). Accordingly, claim construction starts with the words of the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1312–14 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "There is a heavy presumption that a claim term conveys its ordinary and customary meaning, which 'is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.'" *Artemi, Ltd. v. Safe-Strap Co.*, No. CIV. 03-3382 JEI/AMD, 2014 WL 3058379, at *1 (D.N.J. July 7, 2014) (Irenas, J.) (quoting *Phillips*, 415 F.3d at 1313). Dictionaries or comparable sources "are often useful to assist in understanding the commonly understood meaning of words." *Phillips*, 415 F.3d at 1322. Importantly, "the person of ordinary skill in the

art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. In short, it is presumed that claim terms mean what they say, and, unless otherwise compelled, the ordinary meaning of claim terms should be adopted. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

When a meaning is unclear or more than one meaning could be assigned, claim terms should be construed "in view of the specification" which "is always highly relevant to the claim construction analysis"—indeed, it is usually "dispositive." *Phillips*, 415 F.3d at 1315 (citations omitted). The specification "is the primary basis for construing the claim" and is in most cases "the best source for understanding a technical term." *Id.*; *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Courts may also consider a patent's prosecution history when construing claims. *Phillips*, 415 F.3d at 1317. Importantly, courts may not import limitations into the claim that are not supported by the claim language, the specification, or the prosecution history. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014) ("add[ing] language without support from the specification or prosecution history, altering otherwise unambiguous claim language, [is] a practice this court has repeatedly rejected."); *see also Phillips,* 415 F.3d at 1312 ("[I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . . we should never know where to stop.") (quoting *McCarty v. Lehigh Val. R.R. Co.*, 160 U.S. 110, 116 (1895)).

Courts may also correct obvious typographical errors in claims "if the correction is not subject to reasonable debate to one of ordinary skill in the art, namely, through claim language and the specification, and the prosecution history does not suggest a different interpretation." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009)

(correcting a scientific formula to require the presence of one molecule instead of two); *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353 (Fed. Cir. 2011) (inserting the word "and" in between two terms where there was sufficient support for the correction in the specification). For example, in *Howmedica Osteonics Corp. v. DePuy Orthopaedics, Inc.*, the court corrected a claim term by changing the word "inner" to "outer" where the claim language, specification and prosecution history supported the correction. 2013 WL 3455727, at *28 (D.N.J. July 9, 2013).

Defendants assert that certain of the disputed claim terms are indefinite. However, whether certain claims are "invalid for indefiniteness" is an invalidity argument that is properly assessed independently of a claim construction decision. *TransWeb, LLC v. 3M Innovative Properties Co.*, No. CIV.A. 10-4413 GEB, 2011 WL 5825782, at *3 (D.N.J. Nov. 16, 2011) ("[The] indefiniteness argument is inappropriate at the claim construction stage.") (quoting *Intergraph Hardware Techs. Co. v. Toshiba Corp.*, 508 F. Supp. 2d 752, 773 n.3 (N.D. Cal. 2007)); *see also O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1359 (Fed. Cir. 2008) ("[T]he purpose of a *Markman* hearing is to determine the meaning of claim terms.") (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)); *Lugus IP, LLC v. Volvo Car Corp.*, No. CIV.A. 12-2906 JEI, 2014 WL 2094086, at *7 (D.N.J. May 20, 2014) (Irenas, J.) (same); *see also United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-CV-01617, 2014 WL 4259153, at *1 (D.N.J. Aug. 29, 2014) (issuing a decision on indefiniteness after a 14-day bench trial and post-trial briefing on infringement and validity, more than a year after its claim construction ruling); *In re TR Labs Patent Litig.*, No. CIV.A. 09-3883-PGS, 2014 WL 3500596, at *7 (D.N.J. July 14, 2014) (issuing a decision on indefiniteness on summary judgment, separate from its claim construction

decision). Plaintiffs therefore, respectfully assert that because indefiniteness is an entirely separate invalidity issue, it is not appropriate to address it at this claim construction stage.

Moreover, a claim is not indefinite merely because its scope is not ascertainable from the face of the claims. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) ("Of course, claims are not indefinite merely because they present a difficult task of claim construction."). Rather, as the Supreme Court confirmed, the standard for definiteness is whether the claims, when "read in light of the patent's specification and prosecution history . . . inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The Court emphasized that this standard "mandates clarity, while recognizing that absolute precision is unattainable." *Id.* at 2129. Moreover, the standard for indefiniteness "accords with opinions of this Court stating that 'the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.'" *Id.* (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916)).

IV. CONSTRUCTION OF THE TERMS OF THE '102 AND '427 PATENTS

A. "semi-solid preparation"

The term "semi-solid preparation" appears in claims 1 and 4 of the '102 Patent. Claim 1 of the '102 patent is directed to:

> **1.** A method of treating a skin disorder, which comprises a step of orally administering to a mammal having the skin disorder, an oral pharmaceutical composition of isotretinoin, which comprises a ***semi-solid preparation*** containing at least two lipidic excipients, at least one of them being hydrophilic having a Hydrophobic Lipidic Balance (HLB) value equal to or greater than 10, the other being an oily vehicle, whereby the at least one hydrophilic lipidic excipient(s) with a HLB value of at least 10 is selected from the group consisting of glycerol macrogolglycerides; the composition being administered in an amount effective to treat the skin disorder, and wherein the skin disorder is selected from the group consisting of acne, hypertrophic lupus erythematosus, basal cell carcinoma and squamous cell carcinoma.

('102 Patent col. 11 ll. 42-55 (emphasis added).) Claim 4 is directed to "[t]he method of claim **1**, wherein the composition comprises a ***semi-solid preparation*** in which the isotretinoin is partially in suspension and/or partially in solution." (*Id.* col. 11 ll. 62-64 (emphasis added).) The parties' proposed constructions of this term from the Joint Claim Construction and Prehearing Statement ("JCCPS") are set forth below:

"semi-solid preparation"	
Plaintiffs' Construction	**Defendants' Construction**
Plain meaning: a semi-solid composition	A semi-solid suspension, emulsion, microemulsion, self-emulsifying drug delivery system (SEDDS), or self-emulsifying microemulsion drug delivery system (SMEDDS).

Plaintiffs assert that this claim term should be given its ordinary, plain meaning as understood by a person of ordinary skill in the art, namely a semi-solid composition. (*See* Davies Decl. at ¶ 33.) As noted *supra*, a court should presume that the terms in a claim mean what they say, and, unless otherwise compelled, should adopt the ordinary meaning of claim terms. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

Furthermore, this construction is supported by the claims and specification of the patent, which use the terms "preparation" and "composition" interchangeably. For instance, dependent claim 5 uses the phrase "oily vehicle of the ***composition***," while claim 1 states "a semi-solid ***preparation*** containing . . . an oily vehicle." ('102 Patent col. col. 11 ll. 42-55.) Additionally, the patent specification describing the invented semi-solid preparation begins with the title "PHARMACEUTICAL **SEMI-SOLID COMPOSITION** OF ISOTRETINOIN." ('102 Patent col. 1 ll. 1-2 (emphasis added).) The specification also refers to "other isotretinoin preparations" that were "described in the literature" ('102 Patent col. 10 ll. 50-52), which the specification elsewhere terms "compositions" ('102 Patent col. col. 1 ll. 49-60). The fact that the claims and specification use the words "preparation" and "composition" interchangeably further supports

Plaintiffs' assertion that this Court should construe the word "preparation" to mean "composition." *In re Omeprazole Patent Litig.*, 84 F. App'x 76, 80–81 (Fed. Cir. 2003) (affirming the lower court's construction of the terms "pH-buffering alkaline compound" and "pH-buffering alkaline reacting compound" to mean "alkaline reacting compound" where the three terms were used interchangeably in the claims and the specification); *SourceOne Global Partners, LLC v. KGK Synergize, Inc.*, No. 08 C 7403, 2010 WL 2232944, at *4 (N.D. Ill. June 3, 2010) (construing the word "composition" to mean "a formulation or preparation" where the patent "repeatedly refers to the invention as a formulation or preparation of various substances").

Moreover, Defendants themselves treat the terms "semi-solid preparation" and "semi-solid composition" interchangeably in their own claim constructions. Here, Defendants assert that a semi-solid suspension is a type of "***semi-solid preparation***," and as noted *infra*, defendants define "semi-solid suspension" as a type of "***semi-solid composition***," without distinguishing any difference between the two. Defendants, thus, implicitly acknowledge that the term "semi-solid preparation" means "semi-solid composition" within the patent.

Defendants' proposed construction improperly imports limitations into the claims, by stating that "semi-solid preparation" can only mean a "semi-solid suspension, emulsion, microemulsion, self-emulsifying drug delivery system (SEDDS), or self-emulsifying microemulsion drug delivery system (SMEDDS)." Defendants' construction was transparently lifted from a sentence within the specification stating in its entirety: "These systems ***may*** consist of suspension, emulsion, microemulsion, self-emulsifying drug delivery systems (SEDDS®) or self-emulsifying microemulsion drug delivery system (SMEDDS®)." ('102 Patent col. 3 ll. 43-46 (emphasis added).) Defendants, however, inexplicably disregarded the phrase "***may*** consist of" in their construction, instead attempting to convince the Court that this means the invention

only consists of those types of preparations. Defendants ignored entirely the supporting claim language, the title of the patent specifications, and the general descriptions of the invention within the patent, excerpted *supra*, instead choosing to cherry pick favorable portions of the specification to build limitations into the claim term. As stated above, courts should not import limitations into the claim that are not supported by the claim language, the specification, or the prosecution history. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014). Accordingly, this Court should construe the claim term "semi-solid preparation" according to its plain meaning, as supported by the specification of the '102 Patent.

B. "semi-solid suspension"

The term "semi-solid suspension" appears in claim 13 of the '102 patent and claim 1 of the '427 patent. Claim 13 of the '102 patent is directed to "[t]he method of claim **1**, wherein the composition is a ***semi-solid suspension***." ('102 Patent col. 13 ll. 1-2 (emphasis added).) Claim 1 of the '427 patent is directed to:

> **1.** An oral pharmaceutical composition of isotretinoin contained in a pharmaceutically acceptable capsule which comprises a ***semi-solid suspension*** containing at least two lipidic excipients, at least in an amount of about 20 to 80% of one being hydrophilic having a HLB value equal to or greater than 10 selected from the group consisting of glyceroyl macrogolglycerides, polyethylene glycol esters, and mixtures thereof; the other in an amount of about 5 to 70% and being an oily vehicle selected from the group consisting of vegetable oils, medium chain triglycerides, fatty acid esters, glycerol oleate and mixtures thereof; and an amount of about 1 to 10% of at least one additional surfactant.

('427 Patent col. 11 ll. 46-58 (emphasis added).) The proposed constructions are as follows:

"semi-solid suspension"	
Plaintiffs' Construction	**Defendants' Construction**
Plain meaning: a semi-solid composition wherein the preparation is in the form of a suspension.	A semi-solid composition in which isotretinoin is predominantly undissolved and is dispersed in the at least two lipidic excipients.

Plaintiffs assert that this term should also be construed according to its plain meaning, namely as a semi-solid composition wherein the preparation is in the form of a suspension. (*See* Davies Decl. at ¶ 54.) *Artemi, Ltd. v. Safe-Strap Co.*, No. CIV. 03-3382 JEI/AMD, 2014 WL 3058379, at *1 (D.N.J. July 7, 2014) (Irenas, J.) ("There is a heavy presumption that a claim term conveys its ordinary and customary meaning, which 'is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.'") (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

The term "suspension" is a fundamental term in formulation chemistry that is readily understood by persons of ordinary skill in the art. (*See* Davies Decl. at ¶ 54.) As such, this term should be construed according to its plain meaning, and the word "suspension" requires no construction. *AstraZeneca LP v. Breath Ltd.*, No. 09-1518, 2013 WL 1385224, at *6 (D.N.J. Apr. 3, 2013), *aff'd in part*, 542 F. App'x 971 (Fed. Cir. 2013) ("'Suspension' requires no construction and should be accorded its plain meaning"); *Mars, Inc. v. JCM Am. Corp.*, No. CIV. 05-3165(RBK), 2008 WL 2684118, at *8 (D.N.J. July 2, 2008), *aff'd*, 374 F. App'x 956 (Fed. Cir. 2010) (agreeing with the plaintiff that a claim term "would have been readily understandable to . . . a person of ordinary skill in the art" and therefore concluding that: "The Court will not attempt to explicate the meaning of an already clear phrase and thereby risk altering the scope of the claim.") (citing *Scripps Clinic v. Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991) ("the construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.")). The specifications also use the term consistent with its plain meaning, stating without qualification that: "The active ingredient may also be formulated as a suspension . . . ." (*See, e.g.*, '102 Patent

col. 3 ll. 5-7; '427 Patent col. 2 ll. 62-64.) Thus, the plain meaning of the term is also supported by the "highly relevant" and usually "dispositive" specifications. *Phillips*, 415 F.3d at 1315.

Defendants, on the other hand, argue that this Court should import into this claim term a specific limitation that in fact *directly contradicts multiple statements in the patent specifications*. In particular, Defendants' baldly assert that the patents require the isotretinoin to be "predominantly undissolved" when in suspension. In actuality, however, the patents state: "***For suspensions, it was possible to dissolve a high fraction of isotretinoin*** in the mix of excipients ***and even the whole quantity of the active ingredient*** if the manufacturing conditions (high temperature and long time of mixing) and the formulations were optimized." ('102 Patent col. 5 ll. 20-25; '427 Patent col. 5 ll. 16-21 (emphasis added).) This is further confirmed throughout the specifications, which state in the "Detailed Description of the Invention" that "***[t]he isotretinoin may be solubilized*** in the mix of excipients ***or partially solubilized***" ('102 Patent col. 3 ll. 4-5; '427 Patent col. 2 ll. 61-62), and again in the "Description of Examples" section that the invention contains excipients that "***totally or partially*** (depending on the ratio between excipients) ***dissolve isotretinoin***" ('102 Patent col. 5 ll. 16-19; '427 Patent col. 5 ll. 12-15 (emphasis added)).

The Court should not be persuaded by Defendants' attempt to import into the claim a limitation that explicitly contradicts multiple statements in the specifications, in direct defiance of fundamental patent law principles. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014) ("add[ing] language without support from the specification or prosecution history, altering otherwise unambiguous claim language, [is] a practice this court has repeatedly rejected."); *Synqor, Inc. v. Artesyn Technologies, Inc.*, No. 2:07-CV-497-TJW-CE, 2010 WL 2991037, at *8 (E.D. Tex. July 26, 2010), *aff'd*, 709 F.3d 1365 (Fed. Cir. 2013)

(rejecting an attempt to add a limitation to a term where doing so "would contradict the specification"); *see also Acco Brands USA, LLC v. Comarco Wireless Technologies, Inc.*, No. C 11-04378 RS, 2013 WL 843447, at *5 (N.D. Cal. Mar. 6, 2013) ("Reading the patent as a whole, Comarco's proposed construction is the only one that does not contradict the specification. It therefore will be adopted."). Rather, in construing this term the Court should follow the "bedrock principle" of patent law that "[b]ecause the patentee is required to 'define precisely what his invention is,'" "it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *White v. Dunbar*, 119 U.S. 47, 52 (1886)).

C. "hydrophobic lipidic balance (HLB) value"

This term appears in claim 1 of the '102 patent. Claim 1 of the '102 patent is directed to:

> **1.** A method of treating a skin disorder, which comprises a step of orally administering to a mammal having the skin disorder, an oral pharmaceutical composition of isotretinoin, which comprises a semi-solid preparation containing at least two lipidic excipients, at least one of them being hydrophilic having a ***Hydrophobic Lipidic Balance (HLB) value*** equal to or greater than 10, the other being an oily vehicle, whereby the at least one hydrophilic lipidic excipient(s) with a HLB value of at least 10 is selected from the group consisting of glycerol macrogolglycerides; the composition being administered in an amount effective to treat the skin disorder, and wherein the skin disorder is selected from the group consisting of acne, hypertrophic lupus erythematosus, basal cell carcinoma and squamous cell carcinoma.

('102 Patent col. 11 ll. 42-55 (emphasis added).) The parties' proposed constructions of this term are set forth below:

"hydrophobic lipidic balance (HLB) value"	
Plaintiffs' Construction	**Defendants' Construction**
hydrophilic lipophilic balance (HLB) value	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. Defendants submit that this term is not amenable to construction.

Plaintiffs contend that the term "hydrophobic lipidic balance (HLB) value" contains an obvious two-letter typographical error (phobic versus philic) that this Court should correct in its claim construction decision. As stated *supra*, courts may correct obvious typographical errors in claims "if the correction is not subject to reasonable debate to one of ordinary skill in the art, namely, through claim language and the specification, and the prosecution history does not suggest a different interpretation." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009) (correcting a scientific formula to require the presence of one molecule instead of two). For example, in *Howmedica Osteonics Corp. v. DePuy Orthopaedics, Inc.*, the Court corrected a claim term by changing the word "inner" to "outer" where the claim language, specification and prosecution history supported the correction. 2013 WL 3455727, at *28 (D.N.J. July 9, 2013).

Plaintiffs' position that this claim term contains a two-letter typographical error is supported by the '102 patent and its prosecution history. (*See, e.g.*, '102 Patent col. 3 ll. 13-24, col. 4 ll. 15-23, col. 5 ll. 13-33, col. 6 ll. 24-27, col. 11 ll. 45-48; Davies Decl. Ex. 22, '102 Patent File History Excerpt at RANB00000217-39, 258-69, 292-99, 319-21.) First, the specification itself introduces the term HLB as the "hydrophilic/lipophilic balance value (HLB)." ('102 Patent col. 3 ll. 14-17.) *Id.* at *3 (rejecting a proposed claim construction because the "interpretation [could] not be reconciled with the language of the specification.") Moreover, the claim itself states "a semi-solid preparation containing at least two lipidic excipients, at least ***one of them being hydrophilic having a*** Hydrophobic Lipidic Balance ***(HLB) value equal to or greater than 10***." ('102 Patent col. 11 ll. 45-48 (emphasis added).) If the "H" in HLB stood for hydrophobic rather than hydrophilic, an excipient with an HLB value greater than 10 would not be hydrophilic as stated in the claim. *Artemi, Ltd. v. Safe-Strap Co.*, No. CIV. 03-3382

JEI/AMD, 2014 WL 3058379, at *4 (D.N.J. July 7, 2014) (Irenas, J.) (rejecting a proposed claim construction where the proponent could "[]not reconcile its proposed construction with the rest of the term.")

The prosecution history of the '102 patent even more clearly illuminates the error. In an Amendment filed on December 7, 2011, applicants amended pending-claim 14 to contain the phrase "at least one of them being ***hydrophilic*** having a ***Hydrophilic Lipidic Balance (HLB)*** value equal to or greater than 10." (Davies Decl. Ex. 22, '102 Patent File History, RANB00000001-362 at RANB00000222 (emphasis added).) A subsequent Amendment filed on May 16, 2012, however, introduced the typographical error; the "Previously Presented" claim subsequently read "at least one of them being ***hydrophobic*** having a ***Hydrophobic Lipidic Balance (HLB)*** value equal to or greater than 10." This typographical error was maintained when pending-claim 14 was cancelled and pending-claim 37, the predecessor to claim 1, was introduced, containing the same phrase. The examiner eventually noticed the typographical error and in the Notice of Allowability stated that the claim "should be amended by replacing the term 'hydrophobic' in line 4 with the term --hydrophilic--." (*Id.* at RANB00000320.) However, despite these instructions, only the first instance of the term "hydrophobic" in line 4 was replaced, and the second instance of the term in line 4, in "Hydrophobic Lipidic Balance (HLB)" was mistakenly not:

> 37. (New) A method of treating a skin disorder, which comprises a step of orally administering to a mammal having the skin disorder, an oral pharmaceutical composition of isotretinoin, which comprises a semi-solid preparation containing at least two lipidic excipients, at least one of them being hydrophobic having a Hydrophobic Lipidic Balance (HLB) value equal to or greater than 10, the other being an oily vehicle, whereby the at least one hydrophilic lipidic excipient(s) with a HLB value of at least 10 is selected from the group consisting of glycerol macrogolglycerides; the composition being administered in an amount effective to treat the skin disorder, and
>
> wherein the skin disorder is selected from the group consisting of acne, hypertrophic lupus erythematosus, basal cell carcinoma and squamous cell carcinoma.

(*Id.* at RANB00000296 (emphasis added).)

Finally, as thoroughly explained by Dr. Davies, a person of ordinary skill in the art would readily understand that this is a two-letter typographic error. Citing a multitude of scientific textbooks and articles, Dr. Davies explained that HLB is a commonly used acronym standing for Hydrophilic Lipidic Balance. (Davies Decl. at ¶ 44–45.)

This Court should correct this term to read "Hydrophilic Lipidic Balance (HLB)" as supported by the patent claims, specification and prosecution history, and as confirmed by the opinion of a person of ordinary skill in the art. *See Howmedica Osteonics Corp. v. DePuy Orthopaedics, Inc.*, 2013 WL 3455727, at *28 (D.N.J. July 9, 2013).

D. "the isotretinoin is partially in suspension and/or partially in solution"

The term "the isotretinoin is partially in suspension and/or partially in solution" appears in claim 4 of the '102 patent. Claim 4 is directed to "[t]he method of claim **1**, wherein the composition comprises a semi-solid preparation in which ***the isotretinoin is partially in suspension and/or partially in solution***." ('102 Patent col. 11 ll. 62-64 (emphasis added).) The parties' proposed constructions are as follows:

"the isotretinoin is partially in suspension and/or partially in solution"	
Plaintiffs' Construction	**Defendants' Construction**
Plain meaning: a preparation in which the isotretinoin is partially in suspension wherein at least some particles of isotretinoin are not dissolved and/or is partially in solution wherein at least some particles of isotretinoin are dissolved.	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. While Defendants submit that the term is not amenable to construction, if the term were construable, the most logical meaning would be "(1) a dispersion in which the isotretinoin is partially undissolved and partially dissolved in the at least two lipidic excipients; or (2) a dispersion in which the isotretinoin is partially undissolved in the at least two lipidic excipients or the isotretinoin is partially dissolved in the at least two lipidic excipients, and the remaining isotretinoin is neither in suspension nor in solution."

Plaintiffs assert that this claim term should be given its plain meaning, according to the principles of claim construction. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc) (stating that the ordinary and customary meaning of claim terms "provide[s] substantial guidance as to the meaning of [the] claim term[].")

A person of ordinary skill in the art would readily understand this claim term. (Davies Decl. at ¶ 48.) This claim term explains, in simple language, that claim 4 of the '102 patent covers products where the isotretinoin is (1) partially in solution; (2) partially in suspension; and (3) partially in solution and partially in suspension. If, however, a product contains isotretinoin that is neither partially in solution nor partially in suspension, then according to the claim language that product would not infringe.

The State of Isotretinoin in the Semi-Solid Preparation	**Infringement**
Partially in solution	✓
Partially in suspension	✓
Partially in solution and partially in suspension	✓
Neither partially in solution nor partially in suspension	×

Plaintiffs' construction is further supported by the specification, which states that "[t]he isotretinoin may be solubilized in the mix of excipients or partially solubilized ('102 Patent col. 3 ll. 5-6) and that the "excipients . . . totally or partially (depending on the ratio between

excipients) dissolve isotretinoin" (*id.* col. 5 ll. 16-19). Thus, a person of ordinary skill in the art would understand based on the specification that the scope of claim 4 covers, among other things, a semi-solid preparation where the isotretinoin is partially dissolved in the composition.

Defendants assert in their proposed claim construction that this claim term is indefinite. As discussed above, indefiniteness is an entirely separate invalidity issue that is not appropriate to address at the claim construction stage. (*See* Section III, *supra*.) As such, this Court should disregard Defendants' indefiniteness argument at this stage, and reject its alternate claim construction—which, as explained below, is a thinly veiled attempt to mislead the Court into thinking that the claim term is indefinite. Moreover, even if the Court could properly determine indefiniteness at the claim construction stage, Defendants' assertion that the claim is indefinite is meritless. The plain meaning of the phrase is readily ascertainable to persons of ordinary skill in the art, who would understand the meaning of the basic scientific concepts "partially in suspension" (meaning at least some particles of isotretinoin would be in suspension) and "partially in solution" (meaning at least some particles of isotretinoin would be dissolved) and would be able to conceptually combine the phrases using the connector "and/or." (Davies Decl. at ¶¶ 48–49.) As noted *supra*, a claim is not indefinite merely because one party asserts that its scope is not ascertainable from the face of the claims. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Additionally, while the definiteness requirement "mandates clarity," courts must "recognize[e] that absolute precision is unattainable" and that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). In this case, the plain meaning is both readily ascertainable and reasonable to a person of ordinary

skill in the art who would be familiar with these basic scientific concepts. (Davies Decl. at ¶¶ 48–49.)

Far from being "the most logical meaning," Defendants have taken a relatively simple claim term and proposed an arduous, incorrect definition that is redundant, self-contradictory, and imports limitations into the term that are not supported by the patent. Defendants' construction reads: "(1) a dispersion in which the isotretinoin is partially undissolved ***and*** partially dissolved in the at least two lipidic excipients; ***or*** (2) a dispersion in which the isotretinoin is partially undissolved in the at least two lipidic excipients ***or*** the isotretinoin is partially dissolved in the at least two lipidic excipients, ***and*** the remaining isotretinoin is ***neither*** in suspension ***nor*** in solution." (Emphasis added.) For one, the phrase "partially undissolved and partially dissolved" is redundant—if isotretinoin is partially undissolved, then logically part of it is dissolved. Second, inclusion of the phrase "in the at least two lipidic excipients" imports a limitation into the claim that is not supported by the specification, by requiring the dissolution to occur in all excipients, rather than simply in the whole preparation. Finally, the second phrase in part (2) of Defendants' definition, namely "the isotretinoin is ***partially dissolved*** . . ., and the remaining isotretinoin is neither in suspension ***nor in solution***" is redundant—if isotretinoin is "partially dissolved," then logically the remaining isotretinoin is not dissolved, meaning that it is by definition "no[t] in solution." (Davies Decl. at ¶ 51.)

This Court should reject Defendants' assertions that the simple phrase "the isotretinoin is partially in suspension and/or partially in solution" is either indefinite or should be given a redundant, self-contradictory meaning. Instead, this Court should follow the decades of Federal Circuit precedent stating that the words of a claim "are generally given their ordinary and

customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

E. "an amount of about 1 to 10% of at least one additional surfactant" and "about 1-10% of an additional surfactant"

The term "an amount of about 1 to 10% of at least one additional surfactant" appears in claim 1 of the '427 patent. The term "about 1-10% of an additional surfactant" appears in claim 12 of the '427 patent. Claim 1 is directed to:

> **1.** An oral pharmaceutical composition of isotretinoin contained in a pharmaceutically acceptable capsule which comprises a semi-solid suspension containing at least two lipidic excipients, at least in an amount of about 20 to 80% of one being hydrophilic having a HLB value equal to or greater than 10 selected from the group consisting of glyceroyl macrogolglycerides, polyethylene glycol esters, and mixtures thereof; the other in an amount of about 5 to 70% and being an oily vehicle selected from the group consisting of vegetable oils, medium chain triglycerides, fatty acid esters, glycerol oleate and mixtures thereof; and ***an amount of about 1 to 10% of at least one additional surfactant***.

('427 Patent col. 11 ll. 46-58 (emphasis added).) Claim 12 is directed to "[t]he pharmaceutical composition of claim **1**, wherein the composition contains about 20-80% by weight of glyceroyl macrogolglycerides, about 5-70% by weight of an oily vehicle and ***about 1-10% of an additional surfactant***." (*Id.* col. 12 l. 66 – col. 13 l. 2 (emphasis added).) The parties' proposed constructions for these terms are as follows:

"an amount of about 1 to 10% of at least one additional surfactant"	
Plaintiffs' Construction	**Defendants' Construction**
An amount of approximately 1 to 10% of at least one additional surface active agent or surface active substance	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. Further, the '427 patent lacks written description support for an amount of surfactant less than 1% and an amount of surfactant greater than 10%. Accordingly, it is Actavis' position that the term should not be construed to encompass subject matter beyond 1 to 10%. While Defendants submit that these terms are not amenable to construction, if the terms were construable, the most logical

	meaning would be "an amount of 0.95% to 10.50% of at least one additional excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic."

"about 1-10% of an additional surfactant"	
Plaintiffs' Construction	**Defendants' Construction**
Approximately 1-10% of an additional surface active agent or surface active substance	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. Further, the '427 patent lacks written description support for an amount of surfactant less than 1% and an amount of surfactant greater than 10%. Accordingly, it is Actavis' position that the term should not be construed to encompass subject matter beyond 1 to 10%. While Defendants submit that these terms are not amenable to construction, if the terms were construable, the most logical meaning would be "an amount of 0.95% to 10.50% of at least one additional excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic."

Plaintiffs assert that these terms should be construed according to basic patent law principles to mean "[An amount of] approximately 1 to 10% of [an/at least one] additional surface active agent or surface active substance." Specifically, the Court should construe the term "about" according to its ordinary meaning.[4] *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc).

The Federal Circuit has routinely held that the ordinary meaning of the term "about" is "approximately." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005) ("We reverse the district court's construction of 'about' [to mean 'exactly'] and hold that such

[4] Plaintiffs are willing to consent to the construction of "surfactant" that was agreed upon in the Joint Claim Construction and Prehearing Statement for '102 Patent Claim 8, in lieu of "surface active agent or surface active substance," to the extent that Defendants dispute this portion of Plaintiffs' construction. Specifically, Plaintiffs are willing to consent to the construction "An excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic."

term should be given its ordinary meaning of 'approximately.'"); *UCB, Inc. v. Mallinckrodt Inc.*, 12-463-LPS, 2013 WL 3871427, at *6 (D. Del. July 25, 2013) (rejecting defendants' proposed construction of "amount of about 20 to 40 percent" to fall within a specific numerical range, instead construing the term to mean "amount of approximately 20 to 40 percent"); *Massachusetts Inst. of Tech. v. Affymetrix, Inc.*, CIV.A. 08-11132-GAO, 2012 WL 3800842 (D. Mass. Sept. 4, 2012), *aff'd*, (Nov. 6, 2013) ("These terms [e.g. ". . . from about 10 to about 50 nucleotide residues"] can be given their plain meaning: "about" means *approximately*."). Additionally, a person of ordinary skill in the art would understand that "about" means "approximately," and common dictionary definitions support that construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322 (Fed. Cir. 2005). (*See* Davies Decl. at ¶ 62.) The claims and specification further support this construction. The specification describes several examples that would fit within the claim limitation: "For example, the composition contains from 1 to 10% by weight of at least one surfactant." ('427 Patent col. 4 ll. 28-37); and an example "Formulation . . . (batch number 26F97/1)" containing the surfactant "Tween 80®" as 28.4% w/w of the formulation ('427 Patent col. 8 ll. 15-23; Davies Decl. at ¶¶ 64–65).

Defendants assert in their proposed claim construction that this claim term is indefinite. As discussed above, indefiniteness is an entirely separate invalidity issue that is not appropriate to address at the claim construction stage. (*See* Section III, *supra*.) Moreover, Defendants' argument that the claim term is indefinite is against the weight of precedent. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005) (construing the terms "about 35 [or 70] mg"); *UCB, Inc. v. Mallinckrodt Inc.*, 12-463-LPS, 2013 WL 3871427 (D. Del. July 25, 2013) (construing the term "amount of about 20 to 40 percent"); *United Therapeutics Corp. v. Sandoz, Inc.*, 3:12-CV-01617, 2013 WL 3223384 (D.N.J. June 25, 2013) (rejecting specifically

defendant's argument that the term "a pH between about 10 to about 12" was indefinite). As the Federal Circuit has articulated, a claim is not indefinite merely because one party asserts that its scope is not ascertainable from the face of the claims. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

Defendants also improperly attempt to insert another invalidity argument during the claim construction phase. In stating "the '427 patent lacks written description support for an amount of surfactant less than 1% and an amount of surfactant greater than 10%," Defendants are asserting an argument under 35 U.S.C. § 112 that is improper to make at the claim construction stage. Instead, according to the principles of claim construction repeatedly reaffirmed by the Federal Circuit, this court should construe the term "about" according to its ordinary meaning unless the patentee expressly acted as his own lexicographer. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005) ("[I]n redefining the meaning of particular claim terms away from their ordinary meaning, [a patentee] must ***clearly express*** that intent in the written description") (emphasis added); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an ***express intent*** to impart a novel meaning, claim terms take on their ordinary meaning.") (emphasis added). Defendants' bald assertion that there is no support in the written description for this term thus falls short of the long-held requirement that in order to redefine a term, the patentee must actually *clearly express* an alternate definition of the term in the specification. Therefore, this Court should construe the term "about" according to its plain meaning of "approximately," because the patentee has not expressly acted as his own lexicographer. In addition, contrary to Defendants' assertion, the patent specification contains an example "Formulation . . . (batch number 26F97/1)" containing

the surfactant "Tween 80®" as 28.4% w/w of the formulation ('427 Patent col. 8 ll. 15-23; Davies Decl. at ¶¶ 64–65).

Finally, Defendants again in a thinly veiled attempt to mislead the Court into thinking that the claim term is indefinite propose a lengthy, illogical alternate construction that plainly misconstrues the term "about" and improperly imports into the claim limitations not supported by the specification. Specifically, Defendants propose the alternate construction of "an amount of 0.95% to 10.50% of at least one additional excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic." Defendants cannot point to a line in the specification mentioning the specific percentages 0.95% or 10.5%. This Court should not import limitations into the claim that are not supported by the claim language, the specification, or the prosecution history. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014); *see also Phillips*, 415 F.3d at 1312; *McCarty v. Lehigh Val. R.R. Co.*, 160 U.S. 110, 116 (1895).

Accordingly, this Court should construe these terms according to their plain meaning to mean "[An amount of] approximately 1 to 10% of [an/at least one] additional surface active agent or surface active substance." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *see also Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005).

F. "having a[n] HLB value equal to or greater than 10" and "has an HLB value of at least [12, 13]"

The term "having a[n] HLB value equal to or greater than 10" appears in claims 1, 2, and 3 of the '427 patent. Claim 1 is directed to:

> **1.** An oral pharmaceutical composition of isotretinoin contained in a pharmaceutically acceptable capsule which comprises a semi-

> solid suspension containing at least two lipidic excipients, at least in an amount of about 20 to 80% of one being hydrophilic ***having a HLB value equal to or greater than 10*** selected from the group consisting of glyceroyl macrogolglycerides, polyethylene glycol esters, and mixtures thereof; the other in an amount of about 5 to 70% and being an oily vehicle selected from the group consisting of vegetable oils, medium chain triglycerides, fatty acid esters, glycerol oleate and mixtures thereof; and an amount of about 1 to 10% of at least one additional surfactant.

('427 Patent col. 11 ll. 46-58 (emphasis added).) Claim 2 is directed to "[t]he pharmaceutical composition of claim **1**, wherein the least one hydrophilic lipidic excipient ***has an HLB value of at least 12***." (*Id.* col. 11 ll. 59-61 (emphasis added).) Claim 3 is directed to "[t]he pharmaceutical composition of claim **1**, wherein the least one hydrophilic lipidic excipient ***has an HLB value of at least 13***." (*Id.* col. 11 ll. 62-64 (emphasis added).) The parties' proposed constructions are set forth in the following tables:

"having a[n] HLB value equal to or greater than 10"	
Plaintiffs' Construction	**Defendants' Construction**
Plain meaning: having a hydrophilic lipophilic balance value equal to or greater than 10	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. Defendants submit that this term is not amenable to construction.

"has an HLB value of at least [12, 13]"	
Plaintiffs' Construction	**Defendants' Construction**
Plain meaning: has a hydrophilic lipophilic balance value of at least [12, 13]	Indefinite, as the claims fail to inform with reasonable certainty, those skilled in the art about the scope of the invention. Defendants submit that this term is not amenable to construction.

Plaintiffs submit that these terms should be construed according to their plain meanings. As discussed more fully *supra* in Section IV.C, the acronym HLB is a common term in the art meaning "hydrophilic lipophilic balance," and persons of ordinary skill in the art would understand the acronym HLB in the claims according to this plain meaning. (*See also* Davies

Decl. at ¶ 44.) The patent itself discloses commercial excipients with HLB values greater than 10, including lauroyl macrogol-32 glycerides (Gelucire® 44/14) and stearoyl macrogol-32 glycerides (Gelucire® 50/13), having HLB values of 14 and 13, respectively. ('427 Patent col. 5 ll. 9-24; '102 Patent col. 5 ll. 13-28.) Moreover, because the meaning and calculation of HLB values are commonly known in the art, there are over 2,800 patents with claims directed to surfactants with specific HLB values. (*See* Davies Decl. at ¶ 72 (citing numerous patents containing claims directed to surfactants with specific HLB values).) Additionally, the Board of Patent Appeals and Interferences and the Patent Trial and Appeal Board have repeatedly upheld claims directed to surfactants having HLB values within specified ranges. *See, e.g.*, *Ex Parte Odile Aubrun-Sonneville & Carole Guiramand*, APPEAL 2012-005223, 2013 WL 5740852 (Patent Tr. & App. Bd. Oct. 21, 2013) (upholding a claim term requiring a "surfactant which is liquid at a temperature of 45°C and an HLB of 10 - 15"); *Ex Parte Thomas J. Klofta & Alrick v. Warner*, APPEAL 2001-1242, 2001 WL 34033185 (Bd. Pat. App. & Interf. Feb. 5, 2001) (upholding a claim requiring a "surfactant having an HLB value of at least about 4").

Defendants assert in their proposed claim construction that this claim term is indefinite. As discussed above, indefiniteness is a separate invalidity issue that is not appropriate to address at the claim construction stage. (*See* Section III, *supra*.) Moreover, even if the Court could properly determine indefiniteness at the claim construction stage, Defendants' assertion that the claim is indefinite is meritless. Defendants' argument that these claim terms are indefinite is predicated on the extraordinary assumption that persons of ordinary skill in the art would not know which method to use to calculate HLB values. In support of its arguments, Defendants cite six scientific documents, none of which support Defendants' argument. (*See* Davies Decl. at ¶¶ 74–75.) Rather, each cites specifically to the same widely accepted Griffin method for

calculating HLB values, providing persons of ordinary skill in the art with a tried and true method for determining HLB values. (*See e.g.*, Ex. 34 at 367 ("Other scales of HLB have been developed, although none has gained the acceptance afforded the HLB system of Griffin."); *see also* Davies Decl. at ¶¶ 74–75.) Tellingly, Defendants propose no alternate construction of this widely accepted claim language, for which there is no plausible alternate construction.

In construing these terms, the Court should take into account the immense amount of precedent showing that claim terms describing surfactants using HLB values are valid and definable. Accordingly, the Court should construe the terms according to their plain meanings, following the "bedrock principle" of patent law that "[b]ecause the patentee is required to 'define precisely what his invention is,'" "it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *White v. Dunbar*, 119 U.S. 47, 52 (1886)).

G. "about 10-20 mg of the composition"

The term "about 10-20 mg of the composition" appears in claim 10 of the '427 patent. Claim 10 is directed to "[a] method of administering the pharmaceutical composition of claim **1**, which comprises administering to a human about 10-20 mg of the composition for a total daily dose." ('427 Patent col. 12 ll. 61-63.) The parties' proposed constructions are set forth below:

"about 10-20 mg of the composition"	
Plaintiffs' Construction	**Defendants' Construction**
Approximately 10-20 mg of the active ingredient contained within the composition of claim 1.	It is Actavis' position that this term does not require construction, because it has no bearing on the issues of infringement and invalidity.

Plaintiffs assert that this term should be construed according to its plain meaning, namely approximately[5] 10-20 mg of the active ingredient contained within the composition of claim 1. This claim construction is supported by statements in the specification, such as a description of an example "Formulation of isotretinoin 16 mg (mg/capsule)" with "the dose of 16 mg of the formulation corresponding to the present invention." ('427 Patent col. 10 ll. 33-48 (emphasis added).) Thus, the specification refers to the amount of the composition using the amount of the active ingredient isotretinoin, despite containing different mg/capsule amounts of other ingredients. (*Id.*) Additionally, one of ordinary skill in the art would understand from the claim language and statements in the specification that the milligram (mg) amount of the composition would refer to the milligram amount of the active ingredient in the composition. (*see* Davies Decl. at ¶¶ 78–79.)

It is unclear why Defendants take the position that this term has no bearing on the issues of infringement and validity and why they refuse to provide a proposed construction.

V. CONCLUSION

Based on the foregoing reasons, Plaintiffs respectfully request that the Court adopt Plaintiffs' proposed constructions.

Respectfully Submitted,

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[5] See Section IV.E, *supra*, for a discussion regarding the construction of the term "about" as "approximately" according to its plain meaning.

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Dated: November 14, 2014

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was electronically filed with the Clerk of the Court by using the Court's CM/ECF system, and accordingly served all parties who receive notice of the filing via the Court's CM/ECF system and e-mail.

Dated: November 14, 2014

/s/ Theodora McCormick
Theodora McCormick